Region 2 Caribbean Environmental Protection Division
Multimedia Permits and Compliance Branch – Air Protection Team

CAA Inspection Report

Inspection Date: November 21, 2022

Facility Name: Medtronic Puerto Rico Inc.

Facility Address: PR-149 Km. 56.3, Villalba, P.R. 00766

Coordinates: Latitude: 18.127261 Longitude: -66.497129

ICIS-Air ID: PR0000007214900005

Facility Contact: Guillermo Medina, EHS Specialist, guillermo.medinaburgos@medtronic.com; Mara Cardona, Site Leader, mara.cardona.vega@medtronic.com; and Elvin J. Vélez Santiago, Facilities Manager, elvin.j.velez.santiago@medtronic.com

EPA Inspector(s): Alex O. Rivera, Lead Inspector, (787) 977-5845, rivera.alex@epa.gov; and Gloria Díaz-Galarza, Inspector In-Training, (787) 977-5882, diaz-galarza.gloria@epa.gov

Permitted Regulatory Program(s) Reviewed:

Ethylene Oxide Emissions Standards for Sterilization Facilities - 40 CFR Part 63 Subpart O

National Emission Standards for Hazardous Air Pollutants (NESHAP) for Reciprocating Internal Combustion Engines – 40 CFR Part 63 Subpart ZZZZ

Puerto Rico Regulations for Control of Atmospheric Pollution (PR RCAP)

I. Facility Description

Medtronic ("Facility") operates as a specialized medical device manufacturing facility. The Facility manufactures leads and catheters that are used in implantable pacemakers and pumps used for the treatment of Parkinson's disease. Prior to use, the leads and catheters must be sterilized, and Medtronic accomplishes sterilization of the leads and catheters by exposure to ethylene oxide (EtO) in its on-site sterilization facility. Medtronic's Villalba facility has been operating for around 48 years. Medtronic began conducting sterilization activities at the facility using EtO around 1997.

II. Inspection Purpose

The scope of the inspection was to determine Medtronic compliance with 40 Code of Federal Regulations (CFR) Part 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities, NESHAP for Reciprocating Internal Combustion Engines – 40 CFR Part 63 Subpart ZZZZ and the PR RCAP.

III. Inspection Summary

EPA Inspector Alex Rivera and EPA Inspector In-Training Gloria Diaz-Galarza ("the Inspectors") arrived at the Facility at around 9:15 AM. The Inspectors were received by Ms. Mara Cardona, Site Leader; and Elvin Vélez, Facilities and Environmental Health and Safety Manager at the Facility North Building lobby. The Inspectors were escorted by Ms. Cardona and Mr. Vélez to the North Building Educational Center room at around 9:30 AM. Other representatives from the Facility were present on the room and joined the inspection opening meeting. The following is the list of Medtronic representatives that participated of the opening meeting Mara Cardona, Elvin Vélez, Guillermo Medina, Mario Molina (Equipment Supervisor), Roberto Pagán (Sterilization Engineer), David Negrón (Sterilization Engineer), Pedro Tricoche (Operations Manager), Vanessa Colón (Senior Human Resources Manager, Sandra Delgado (Manufacturing Director), Jose García (Quality Director), Pedro Santiago (Electrician), Anne Monine (Senior EHS Director) and Patricia Duft[1] (Senior Legal Director). The Inspectors began the inspection opening meeting by showing the inspector credentials, allowing everyone to introduce themselves and explaining the purpose of the visit. Ms. Cardona shared a presentation about the Facility Health and Safety requirements, its mission and general description of their operations. The Facility also offered information about their proposed EtO abatement project. The following is a summary of the information provided:

1. Same project as Medtronic completed in one of their facilities located in Florida.
2. Consist of the installation of dry bed reactors to control the emissions from their sterilization process aeration phase. Two (2) dry bed reactors to be installed in the North Building and one (1) in the South Building.
3. The North and South Buildings have 17 and six (6) sterilizers each. The North Building is divided in two (2) sterilization areas, one with 10 sterilizers and the other with seven (7) sterilizers.

[1] Joined virtually and only during the opening meeting to discuss details about the Facility improvement project.

4. Currently waiting for the necessary emission source construction permit to be issued by DNER[2]. Mr. Vélez informed that he has been in constant communication with DNER.
5. The company informed that the project aims to substantially reduce their EtO emissions and expects an emission reduction of more than 80%.
6. The project contract was already awarded, and the control devices are already in the island. Steel fabrication of project components started off-site to expedite the project once the permit is issued.

Once the improvement project discussion concluded the Inspectors proceeded with the inspection questionnaire. The following is a summary of the topics discussed:

1. Permit status – The company submitted an operating permit renewal application to DNER in 2017 and informed that the issuance of the permit renewal is still pending. [3]
2. The Facility started its operations on September 27, 1974. First sterilization with ethylene oxide started around 1997 with the installation of seven (7) sterilizers. The company gradually installed additional sterilizers in 1999, 2001, and 2003. Since 2003, the Facility utilizes 23 sterilizers that operate five (5) days a week.
3. The Facility sterilization chambers are located in two different buildings, North and South Buildings and three (3) different rooms that are designated as either high-voltage or low-voltage chambers. The North Building has two (2) sterilization rooms, and the South Building has one (1). The high- and low-voltage designations refer to the type of device being sterilized: leads for pacemakers are designated as high-voltage devices, and catheters are designated as low-voltage devices. Each sterilizer is equipped with its own aeration chamber that is located directly beneath the sterilization chamber. Each room has a gas chromatograph (GC) to measure EtO using a series of sampling ports. The sterilization operations at the North Building operate 20 hours and the South Building 24 hours.
4. Devices are sterilized in primary Tyvek packaging prior to placement in final packaging. The devices are placed into a sterilization chamber, and an EtO cartridge is inserted into the sterilizer. Each EtO cartridge contains 127 grams of EtO, which is enough for one sterilization cycle. The cycle consists of conditioning, sterilization, and degassing. Once the sterilization cycle begins, the chamber door is locked, and the chamber is placed under negative pressure. The conditioning phase prepares the devices for sterilization by increasing the temperature and humidity in the chamber. Once the chamber has reached the appropriate conditions, the EtO cartridge is punctured and EtO is injected into the chamber to begin the sterilization phase. After the exposure time is complete, the chamber is degassed to a catalytic oxidizer (abator). Each chamber is vented to a dedicated abator. The chamber is air-washed immediately after degassing to remove additional EtO; the air washing is also vented to the abator. The EtO concentration in the chamber is monitored by a GC, which indicates when air washing has removed all EtO. After sterilization, the devices can be aerated in the sterilization chamber or moved to the adjacent aeration chamber for 2 to 16 hours of aeration time. The abator is turned off automatically during the aeration phase, and aeration phase emissions are vented to the atmosphere. Medtronic uses less than 10 tons of EtO per year and is not required to vent aeration phase emissions to a control

[2] DNER issued an emission source construction and operating permit for the project on November 21, 2022, and December 14, 2022, respectively.

[3] DNER issued an emission source operating permit PFE-RG-76-0217-0107-I-II-O on December 14, 2022.

device. After the cycle is complete, the sterilized devices are placed into final packaging. Abators for each sterilizer are located on the roof of the buildings. The abators use catalyst to remove EtO from the vented emissions and convert it to carbon dioxide and water vapor.

5. The Facility has 1,602 employees.
6. The Facility manufacturers catheters and leads. The sterilization process and recipe depend on the type of product. Product is sterilized in a sterilized breathable packaging that allows the product to be sterilized using less EtO and time possible.
7. All 23 sterilizers used by the Facility are 3M™ Model 5xLe Steri Vac™. Each unit size is equal, 4.8 cubic feet. EtO is supplied in cartridges of 127 grams for every cycle (3M™ Steri-Gas™ Gas Cartridges). The Facility complete all sterilization activities within the units. Each unit is capable of complete the precondition, gas exposure and aeration phases on the sterilization cycle.
8. Sterilization rooms are kept under negative pressure.
9. Once the product is sterilized it is transferred to the quality control area, after the quality control process is completed, it is moved to packaging and then the product is placed on the shipping area.
10. The Facility does not have a standard operating scenario on which a specific number of sterilization units are operated in a daily basis. The Facility explained that they keep several sterilizers out for maintenance and/or validation and that supply chain issues are also affecting the manufacturing process, so they are not near their worst-case scenario of operating the 23 sterilizers simultaneously. Also added that the Facility have never operated under that worst case scenario. Each sterilizer is validated (ensure successful sterilization) in a yearly basis.
11. The Facility typically completes four (4) sterilization cycles of 3.5 hours per day in the North Building and five (5) cycles of 4.5 hours per day. The aeration phases depend on the type of product and varies from 2-16 hours.
12. Each sterilization unit has an individual power supply to manage any power outage. The unit seals itself and stops the process until the power issue is resolved.
13. Each sterilizer has a 3M™ EtO Abator Model 50AN to convert the EtO into CO_2 and water vapor through a heat producing reaction. According to the Facility each abator has a 99+% EtO removal efficiency. Each abator has continuous temperature monitor that generates data every 5 seconds. The continuous temperature monitor is calibrated and validated annually. The abator unit has a set point of 150°C, and the unit is not considered ready if this temperature is not met. Each unit has an alarm (sound and visual) to provide status to the Facility personnel working in the sterilization area and operators in the control room. The abators catalytic material is replaced every three (3) years or earlier if the yearly exhaust monitoring conducted by the Facility exceeds 2.5 ppm. The Facility provided a copy of the monitoring equipment or analyzer that is being used to conduct these yearly exhaust monitoring.
14. The Facility provided copies of the abators malfunction events. Since 2020, 12 malfunction events were recorded, investigated, and addressed.
15. Medtronic uses System Analysis Program (SAP) program to manage and generate records of all operations maintenance tasks
16. The Facility provided copies of their annual and monthly EtO consumption records from 2020-2022. The Facility EtO consumption in 2020 was 7.07 tons, 9.16 tons in 2021, and 4.5 tons during the 1st semester of 2022.
17. The Facility has a gas chromatograph (GC) to measure EtO concentration within the sterilization rooms. The North Building high voltage area GC has eight (8) sampling ports, the North Building

low voltage area has five (5) sampling ports, and the South Building sterilization area has seven (7) sampling ports. These GC units have alarms (sound and visual) to alert when concentrations are higher than expected. Visual alarms are triggered when EtO concentration values reach 2.5 ppm and audible alarms when EtO concentrations values reach 5 ppm. The GC units auto-calibrate in a daily basis. Maintenance is conducted every 6 months to test the alarms. An incident report is prepared when an alarm is triggered. The standard operating procedure is that when an alarm is triggered everyone is removed from the room. The Facility provided copies of the alarm's investigation reports from 2020-2022.

18. A total of 10 employees works at the Facility sterilization areas on two (2) shifts of eight (8) hrs.
19. The Facility conducts annual medical surveillance and mandatory training to all sterilization process employees or any employees that spend more than 30 days in the sterilization areas. The company agreed on providing electronic copies of the training provided to the employees.
20. The Facility sterilization rooms are locked, and only authorized personnel are allowed access.
21. The Facility has four (4) emergency generators in the North Building, three (3) emergency generators in the South Building, and three (3) fire pumps (two (2) at the North Building and one (1) at the South Building).
22. On February 8, 2022, the Facility received an emission source construction permit to install a cogeneration unit. The Facility is in the process of constructing a combined heat and power system that is expected to be in operation by May 2023.

The Inspectors completed the questionnaire portion of the inspection and began the Facility walkthrough at 3:00 PM. The following is a summary of the walkthrough observations in accordance with conversation with the Facility representatives:

a. Not all product manufactured on-site requires to be sterilized, 25-30% of the final product is not sterilized. The Facility representatives also mentioned that for example, catheters are not sterilized on-site, but need EtO sterilization. However, catheters are sterilized using a contract sterilizer service in Puerto Rico.
b. Sterilizing rooms control rooms has GC units and pressure meters to monitor EtO concentrations and negative pressure. The control room has also access to each sterilizer performance data. The Facility provided copy of a sterilizer performance graph providing an example of the data generated during a sterilization cycle.
c. The North Building has a total of four (4) emergency engines, two (2) is the area known as old building and two (2) in the new building. The Facility conducts weekly check of oil levels and monthly maintenance runs. Oil change and belts replacement is done by an external company.
d. The North Building has two (2) sterilization areas known as low voltage and high voltage. Each sterilizer is equipped with its own aeration chamber that is located directly beneath the sterilization chamber, where the secondary aeration phase of the cycle is performed. Each sterilizing area has an exhaust fan to remove air from the secondary aeration phase of the cycle and emit it to the atmosphere. Each sterilizer is connected to an abator to manage the emissions from degassing, air washes and primary aeration and secondary aeration during late night shifts (employees not available to switch product to secondary aeration chamber before completing the shift).

e. Each abator has three (3) different sampling/test ports, for measuring EtO concentrations at inlet, outlet, and for pressure measurement. The Facility has 17 total abators in North Building.
f. A cogeneration unit is under construction at North Building, contractor working on-site. The purpose of the project is to supply 80% of the North Building power demand. The Facility also informed that similar projects are planned for Medtronic facilities in Juncos, Humacao, and Ponce. A solar array is being considered for the South Building.
g. Medtronic Villalba operations does not relate or are dependent of the other Medtronic facilities in the island. As an example, the Facility mentioned that Medtronic Juncos manufactures diabetes related product.
h. Two (2) fire pumps provide service to the North Building.
i. The Facility has seven (7) sterilizers and abators at the South Building. Only six (6) units are in operation, one (1) was taken out of commission.
j. The Facility has three (3) emergency engines at the South Building. Can run the entire South Building with two (2) of the emergency engines.
k. The walkthrough was completed at around 4:30 PM.

IV. Closing Meeting

After completing the walkthrough, the Inspectors were escorted to the North Building Educational Center room to conduct the inspection closing meeting. The Inspector summarized the list of documents to be provided via email. The following is the list of such documents[4]:

1. EtO emission performance graph shared during the inspection opening meeting presentation.
2. Gas Chromatograph malfunction reports from 2020-2022.
3. List of trainings provided to EtO area employees in a yearly basis.
4. Abator 5XL-44N temperature measurements from the month of April 2022 and Abator 5XL-57 temperature measurements from the month of March 2022.
5. Inventory of engines including manufacturing dates, capacity/horsepower, make/model, fuel type and applicable standards.
6. Logs of engines operating hours for CY2021 and YTD2022.

The Inspector expressed gratitude to the Facility representatives for the assistance during the inspection and concluded the inspection at 5:00 PM.

[4] The requested information was provided by Medtronic's Elvin Vélez via email on December 5, 2022.

Inspection Report Sign-off

Inspector's Name: Alex O. Rivera

ALEX RIVERA

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Date: 2023.01.20 12:14:04 -04'00'

Inspector in Training Name: Gloria Díaz-Galarza

GLORIA DIAZ-GALARZA

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Supervisor's Name: Nancy Rodríguez

NANCY RODRIGUEZ

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Date: 2023.01.20 13:08:38 -04'00'